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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|--|---------------------|------------------|
| 10/768,951 | 01/29/2004 | Nalam Madhusudhana Rao | 71914/JPW/AG | 7180 |
| 7590 John P. White Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036 | | EXAMINER SAIDHA, TEKCHAND ART UNIT PAPER NUMBER 1652 | | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | | |
| 3 MONTHS | 02/21/2007 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|------------------------------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/768,951 | RAO ET AL. | |
| | Examiner Tekchand Saidha | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 September 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 18-51 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 29 January 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

1. ***Election/Restriction***

Applicant's election with traverse of Group I (claims 1-17 & 31-34) in reply filed 9/18/2006 is acknowledged.

2. Claims 31-34 belong to group II (claim 31 depends upon claim 18 of Group II) and was inadvertently listed in Group I. This is corrected as follows.

I. Claims 1-17, drawn to **lipase** variants (not lipase gene variant, because the sequences of SEQ ID Nos. 2-6 amino acid sequences and are therefore lipase variants not 'lipase gene variants as claimed'; claim amendment is suggested), classified in class 435, subclass 198.

II. Claims 18-51, drawn to expression vector or host cell **comprising DNA** encoding lipase variants (is the suggested language for these claims), classified in class 435, subclass 252.3.

3. The traversal is on the ground(s) that Group II claims, drawn to gene encoding a lipase and host cell and protein lipase variants of SEQ ID Nos. 2-6 of Group I, are not independent or distinct and would not be undue burden to the Examiner to examine both groups together. This is not found persuasive because depending upon the restricted group (I or II) being examined, additional classes/subclasses have to be searched. For example, Group II claims, drawn to gene encoding the lipase variants, host, will involve searching for additional class 536 & subclass 23.2 for DNA encoding the enzyme, and class 435, subclass 252.3 for host cell and class 435, subclass 320.1 for vector. The class/subclass of Group I & II do not overlap, and the searches are not coextensive, searching for group I does not always gather art for group II as additional classes need to be searched as explained above. In addition all the 5 sequences of SEQ ID Nos. 2-6 will have to be searched from all commercial and US Patent

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data bases. This additional searching as explained above would therefore involve undue burden to the Examiner. The requirement is still deemed proper but not made FINAL in view of the revised restriction requirement.

4. **Claims withdrawn :**

Claims 18-51 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Claims 1-17 are under consideration in this Office Action.

6. **Priority**

Acknowledgment is made of applicants' claim for priority based on an application filed in India on 1.30.2003.

7. **Drawings**

Drawings filed 1/29/2004 are acceptable for examination purposes.

8. **Sequence Rules**

Applicants' submit a new CRF copy and paper copy of the Sequence Listing new sequence listing which are in compliance with the requirements of 37 CFR 1.821 through 1.825. CRF copy and paper copy of the Sequence Listing new sequence listing are made of record.

9. **Claim Rejections - 35 USC § 112 (second paragraph)**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1-17 recite 'lipase gene variants having SEQ ID NO: 2.....SEQ ID NO: 6....'. However, SEQ ID Nos. 2 through 6 are lipase polypeptide variants.... The claims are indefinite for this reason. Amending the claims to recite 'lipase variants' or 'lipase polypeptide variants', will overcome this rejection.

10. Claims 4-5 recites the limitation "wherein $T_{1/2}$ " in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Amending claim 4, for example, to read "Novel variants as claimed in claim 1, wherein said variants have $T_{1/2}$ value in the range of 6 to 677, is suggested.

Claim 5, may be similarly amended.

11. Claims 6-7 recites the limitation "wherein Km value" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Amending claim 6, for example, to read "Novel variants as claimed in claim 1, wherein said variants have Km value in the range of 0.50 to 2.5 mM.

Claim 7, may be similarly amended.

12. Claims 8-11 & 13-15 - similarly, as in paragraphs 10 & 11, recite the limitations 'Kcat', Kcat/Km, 'organic solvent' or 'residual activity' in claim 1 or 4, and for which there is insufficient antecedent basis.

Claims 4-11 & 13-15 are therefore rejected for lack of antecedent basis in the claim.

13. Claim 17 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 16. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the

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other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

14. No claim is allowed. The claims are, however, free of prior art.

15. Since there are several pending issues and the claims require a thorough overall by way of amendments to the claims, to also allow the Applicants to respond to the revised restriction requirement, and also since the Applicants are overseas, an attempt was not made to contact Applicants' representative by telephone to indicate allowable subject matter.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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